DOCUMENT-IDENTIFIER: US 5545209 A
TITLE: Controlled deployment of a medical device

Brief Summary Paragraph Right (2):
Prostheses are used in body lumens that have been occluded or weakened by disease. For example, to treat arterial stenoses, an endovascular stent is implanted to hold the lumen open and to prevent any flaps or dissections on the lumen wall from occluding the lumen. To treat aneurysms, a prosthesis in the form of a graft is attached to healthy portions of the lumen on either side of the aneurysm so that the body of the graft bridges the weakened area. The wall of these grafts is initially permeable, but through clotting action, becomes fluid impermeable. This reduces the pressure in the aneurysm and hence, the likelihood that it will rupture.

Brief Summary Paragraph Right (6):
Embodiments may include one or more of the following features. The balloon is only initially radially constrained. The constraint is an axially slidable sheath which surrounds and partially constrains the balloon from inflation. The sheath is designed to axially slide along a length of the balloon in response to a pressure in the balloon, such that the balloon may be progressively incrementally inflated. The slidable sheath is adapted to slide axially onto a shaft of the catheter so that the sheath may be retrieved from the patient. The constraint is an elastomeric band which surrounds and partially constrains the balloon from inflation. The elastomeric band is disposed over a significant length of the balloon. The elasticity of the elastomeric band varies, e.g., by varying the thickness of the bond, from one end of the balloon to the other to allow progressive incremental inflation of the balloon. The elastomeric band has uniform elasticity over the portion of the balloon on which it is disposed. The elastomeric band is disposed only over a center region of the balloon and divides the balloon into a proximal and a distal region. The tubular prosthesis is a stent. The balloon is substantially nondistendible. The constraint is an axially slidable sheath which surrounds the balloon, the sheath being formed of a low coefficient of friction polymer. The polymer is teflon. The balloon has an inflatable portion corresponding to the length of the prosthesis and the balloon and prosthesis have a length of about 5 cm or more. The balloon and prosthesis have a length in the range of about 8-12 cm. The prosthesis includes a clot inducing fabric. The prosthesis is folded around the balloon and constraint. The catheter includes a single lumen for injection of the inflation fluid. The inflation lumen includes an inflation port for directing fluid into the balloon, the port located at a region corresponding to a portion of the balloon not initially restrained by the constraint.

Brief Summary Paragraph Right (8):
Embodiments may include one or more of the features discussed above with respect to prosthesis delivery systems. Particular embodiments may include one or more of the following. The balloon is substantially nondistendible. The constraint is an axially slidable sheath which surrounds the balloon, the sheath being formed of a low coefficient of friction polymer. The polymer is teflon. The sheath includes an extension to proximal portions of the catheter for controlling the axial location of the sheath. The sheath is adapted to slide axially in response to pressure in the balloon.

Brief Summary Paragraph Right (9):
In another aspect, the invention features a method of expanding a tubular prosthesis with a balloon catheter. The method includes providing a balloon catheter having an inflatable balloon on its exterior. The balloon is inflatable by injection of fluid through a lumen in the catheter. The balloon is initially partially radially restrained against inflation by a slidable sheath which surrounds the balloon. The sheath is adapted to slide axially along the balloon onto the catheter shaft in response to a pressure in the balloon such that the balloon may be progressively

incrementally inflated. A tubular prosthesis is disposed on the catheter over at least a portion of the balloon and a portion of the constraint. The tubular prosthesis has a contracted condition and an expanded condition. The tubular prosthesis is initially disposed on the catheter in the contracted condition. The method further includes inflating the balloon such that an unrestrained portion of the balloon inflates first and causes a portion of the tubular prosthesis disposed over the unrestrained portion to expand and progressively incrementally inflating the constrained portion of the balloon causing a portion of the tubular prosthesis disposed over the restrained portion of the balloon to be progressively incrementally expanded.

Brief Summary Paragraph Right (12):
In another aspect, the invention features a method of performing angioplasty using a balloon catheter. The method includes providing a balloon catheter having an inflatable balloon on its exterior. The balloon is initially partially radially restrained against inflation by a slidable sheath which surrounds the balloon and is inflatable by injection of fluid through a lumen in the catheter. The sheath is adapted to slide axially along the balloon onto the catheter shaft in response to pressure in the balloon such that the balloon may be progressively incrementally inflated. The method further includes inflating an unrestrained portion of the balloon by injecting fluid into the balloon through a lumen in the catheter and then inflating a restrained portion of the balloon by injecting additional fluid into the balloon through the lumen such that the pressure of the fluid inside the balloon incrementally slides a restraining sheath off of the balloon, allowing the balloon to progressively incrementally inflate.

Brief Summary Paragraph Right (19):
The accuracy of stent positioning, particularly with long prostheses, is affected by the unpredictable nature of balloon inflation. A balloon will sometimes begin to inflate from the proximal end and sometimes from the distal end. Since expansion of a stent often results in contraction of the stent length, an irregular, unpredictable expansion introduces more uncertainty in the placement of the ends of the stent. In aspects of the invention, a predictable, controlled inflation and prosthesis expansion is achieved by using constraints.

Brief Summary Paragraph Right (20):
Another problem that can arise while positioning balloon expandable prostheses, again especially those of considerable length and when using nonelastic balloons, is that, after expansion, the balloons do not deflate to their original profile but form folds or "wings" which can be quite rigid. If the balloon must be deflated and moved axially to expand an unexpanded portion of the stent, these wings can drag on the stent and dislodge it. According to aspects of the invention the balloon's length is sized to match the length of the prosthesis and the balloon is inflated only one time to fully expand of the prosthesis. In embodiments, select portions of the balloon are sequentially inflated, as if the catheter carried multiple balloons, yet the system need only include a simple, single inflation lumen catheter.

Drawing Description Paragraph Right (1):
FIG. 1 is a side view of components of an embodiment of the invention, showing a balloon catheter (in partial cross-section), a constraint, and a stent;

Detailed Description Paragraph Right (1):
Referring to FIGS. 1 and 2, an embodiment of the invention for placement of an aortic graft includes a vascular catheter 20 carrying a balloon 10, an inflation constraint 14 in the form of an annular sheath, and a tubular prosthesis 12. Referring particularly to FIG. 2, for delivery into the body, balloon 10 is folded around the catheter body and constraint 14 is positioned so that a short distal portion 13 of the balloon remains unconstrained. Prosthesis 12, in a small diameter condition, is then slipped over this assembly such that it is disposed above the unconstrained distal portion 13 of the balloon and the constraint over the more proximal portions of the balloon. The prosthesis is held in place on both ends by sleeves 22. The balloon can be inflated by the introduction of inflation fluid through an inflation lumen 21 which communicates with the interior of the balloon via an inflation port 17.

Detailed Description Paragraph Right (3):
Inflation constraint 14 is a tubular member of which is shorter than the balloon, e.g., extending about half of the balloon length. The inner diameter of constraint 14 is about equal to the folded profile of the balloon, which is about 3 mm in this

embodiment. The friction fit between the constraint and balloon is sufficient such that the constraint will not move prior to balloon inflation, e.g., during loading of the stent or while the catheter assembly is being inserted into the patient. Yet, the friction is not so great as to prevent axial sliding of the constraint in response to axial forces on the distal end of the constraint which are created during inflation of distal portions of the balloon. The constraint is preferably made of a low friction material such as Teflon.RTM. (low friction TFE Teflon.RTM., available from E. I. Dupont DeNemours Corp., Wilmington, Del.). The low friction inner surface of the constraint, in contact with the balloon 12, facilitates retraction of the sheath during balloon inflation. The constraint and/or the balloon may also include a lubricant to reduce friction. The inner diameter of the constraint is sufficiently large so it will slide onto proximal portions of catheter 20 upon full expansion of balloon 10 and can thus be removed from the body with the catheter after implanting the prosthesis. The wall thickness of the constraint typically ranges from five to seven thousandths of an inch, and preferably is as small as possible so that the overall diameter of the assembled product may be kept small. The thin wall of the constraint allows the pressure of the balloon to cause the distal end of the constraint to flare out slightly, which aids retraction.

Detailed Description Paragraph Right (4):
The constraint is positioned on the balloon so that a distal portion 13 is not constrained. The length of the unconstrained distal portion is sufficient to allow some initial expansion of the balloon. Preferably, the length of the unconstrained portion is sufficient so that the initial expansion of the balloon will expand the distal end of the prosthesis to engage the lumen wall distal of a diseased area. The length of portion 13 may correspond, for example, at least to the expanded diameter of the prosthesis. In embodiments, for a stent with an expanded diameter of about 25 mm, the distal end 24 of the constraint is positioned, L.sub.1, about 4 to 6 cm, e.g. 5 cm from the distal end of the balloon. For a balloon having a 10 cm length (inflating to full expanded diameter) and balloon sleeves of about 1.5 cm, the constraint is about 6 cm in length and initially positioned to cover substantially the length of the proximal sleeve and the proximal 4.5 cm of the balloon, leaving the distal 5.0 cm of the balloon and the 1.5 cm length of the distal sleeve unconstrained and uncovered.

Detailed Description Paragraph Right (6):
Catheter shaft 20 (diameter 0.094 inch) is made from plastic such as nylon, e.g., elastomeric nylon (PEBAX, Atochem Corp., Philadelphia, Pa.), PVC, polyurethane, or any other suitable plastic. Inflation lumen 21 within catheter 20 extends from near the distal end of the balloon to inflation device 28 (FIG. 8). The diameter of catheter shaft 20 is kept as small as possible, yet large enough to accommodate inflation lumen 21 and a guide wire lumen 19. If desired, additional lumens, such as a lumen extending through distal tip 18 for injecting fluid into an aneurysm, or a fibre optic lumen for viewing the procedure, may be included in catheter shaft 20. Distal tip 18 of catheter shaft 20 is preferably an atraumatic tip smoothly shaped to avoid puncture or abrasion of the lumen wall during entry into the body. Embodiments of the system may be constructed to allow the balloon to inflate progressively from the proximal to the distal end, by including an extension on the catheter distal of the balloon to receive the constraint on full inflation, and positioning the sheath to leave a short proximal portion of the balloon unconstrained.

Detailed Description Paragraph Right (8):
Prosthesis 12 is preferably a balloon expandable prosthesis including clot inducing fabric strands co-knit with metal strands as taught in U.S. patent application Ser. No. 07/912,902, filed Jul. 13, 1992, which is incorporated herein by reference. The invention is particularly suitable for use with folded fabric-containing prosthesis which can twist about the catheter if not progressively expanded. Knitted stents are particularly suitable for extended lengths because of their high flexibility which allows the stent to conform to the sometimes torturous path of the lumen. Other suitable prostheses include for example, the Strecker stent, a balloon expandable knitted stent described in U.S. Pat. No. 4,922,905; the Palmaz stent described in U.S. Pat. No. 4,776,337; and the Parodi prosthesis in which a dacron graft is sewed between two stents, as described in European Pat. App. No. 91-304988.8. All of these cases are incorporated herein by reference. Prosthesis retaining sleeves (e.g. formed of SILASTIC, Dow Corning Corp., Midland, Mich.) of suitable construction are discussed in Savin U.S. Pat. No. 4,950,227, the entire contents of which is hereby incorporated by reference.

Detailed Description Paragraph Right (9):
Referring to FIG. 8, the invention may be used for the treatment of aortic aneurysms. A physician accesses the femoral artery by either a cutdown or percutaneous access and bleeding is managed by an access sheath 32 equipped with a hemostasis valve such as the PINNACLE hemostasis valve (Boston Scientific Corp. of Watertown, Mass.). A guidewire 30 is passed through the access sheath into the femoral artery, through the iliac artery and into the abdominal aorta. A catheter of the invention (configured as in FIG. 2) is passed over the guide wire and positioned about the aneursym. The partially constrained balloon is inflated by attaching an inflation device 28 to a port of inflation lumen 21 on the proximal end of catheter 20. The inflation device is preferably a LEVEEN screw syringe (Boston Scientific Corp.) which enables accurate displacement of a volume at high pressures of between six and twenty atmospheres. Fluid, such as a water-saline-renographic mixture, is used to inflate balloon 10. A constrast agent, e.g., RENOGRAFIN, (Squibb Diagnostics Inc., Princeton N.J.), visible under fluoroscopy, allows the controlled inflation of the device to be monitored.

Detailed Description Paragraph Right (10):
Referring to FIGS. 3-6, the prosthesis may be progressively expanded. As fluid is injected into the balloon, the distal portion of the balloon, which is not covered by the constraint 14, inflates and expands the corresponding portion of the prosthesis (FIG. 3). Because this unconstrained distal portion of the balloon is always the first part of the balloon to expand, the distal end of the prosthesis may be accurately and reliably positioned on healthy lumen tissue distal of the aneurysm. The expanded portion of the prosthesis engages the aortic wall and provides an anchor which holds the stent in place during subsequent inflation and expansion. The radial force from the pressure inside the balloon secures the distal segment of the stent in this position. (As illustrated, on expansion, the prosthesis may shrink somewhat axially, drawing this portion of the stent positioned over the balloon sleeves over the working surface of the balloon.)

Detailed Description Paragraph Right (11):
Injection of additional fluid (without prior deflation of the balloon) causes constraint 14 to slide (arrow 23) axially proximally (FIGS. 4 and 5), allowing expansion of the proximal portions of the prosthesis in an automatic, progressive, and controlled manner. After continued inflation, constraint 14 is positioned over the catheter body and is no longer in contact with balloon 10 (FIG. 6). (Again, axial contraction of the stent draws the proximal end distally during expansion.) Complete inflation of the balloon allows complete expansion of the stent so that the proximal end of the stent will be secured to healthy lumen tissue proximal of the aneurysm. Careful introduction of fluid using, e.g., a screw syringe, allows the length of balloon inflated, and the length of the prosthesis expanded, to be carefully controlled. For example, each turn of the syringe may move the constraint an additional distance, e.g., 1 mm, exposing and inflating a corresponding length of the balloon.

Detailed Description Paragraph Right (17):
In other embodiments, more than one constraint is used so that a central portion of the stent may be first expanded. In this embodiment either slidable sleeves are incrementally axially displaced from each end of the balloon by the wedging action or elastic constraints on both ends of the balloon are overcome by internal pressure in the balloon.

Detailed Description Paragraph Right (18):
In other embodiments, the constraint may be such that it is axially moveable and manipulable from proximal portions of the catheter remaining outside the body. The constraint may be constructed as a sheath that runs the full length of the catheter or is controlled by a wire extending through an additional lumen in the catheter. The constraint is manually withdrawn to effect a desired length of inflation and expansion of the graft. The constraint may also initially extend over the full length of the balloon. The full-length constraint can be withdrawn axially a short distance, then the balloon inflated, allowing progressive automatic expansion of the prosthesis as the constraint slides distally or the constraint may be manually retracted a desired distance and located so only a desired length of the balloon will inflate. The catheter body may also include adjustable stops which limit the axial travel of the constraint. These stops may be adjustable from the proximal portion of the device.

Detailed Description Paragraph Right (32):

In still other embodiments, the resistance to inflation provided by the constraint may be controlled by providing circumferential ribs or grooves along the sleeve, with fewer ribs provided at the distal portion, compared to the proximal portion, and still fewer ribs in the middle portion. In other embodiments, the sleeve may include circumferential slits. In other embodiments, the system may be provided with a stent positioned over the constraint and which is expanded by sequentially expanding the distal, proximal, and middle portions. The constraint can be constructed to permit expansion of portions in sequences other than those described above. For example, the constraint may permit a sequential inflation of only two balloon portions, e.g. distal followed by proximal. The systems can be adapted for use in other parts of the body, particularly where rapid, blind positioning and dilatation is desirable, such as in the gastrointestinal tract.

Other Reference Publication (3):
Camacho et al., "Double-Ended Pigtail Ureteral Stent: Useful Modification to Single end Ureteral Stent", Urology, 13:516-520, May 1979.

Other Reference Publication (5):
Becker and Schellhammer, "Placement of Double-Pigtail Ureteral Stent Via Cystoscope", Urologoy, 20:310-311, Sep. 1982.

CLAIMS:

1. A prosthesis delivery system comprising:

a ballon catheter extending over a length and having an inflatable balloon on its exterior, said balloon being inflatable by injection of fluid through a lumen in said catheter, and said balloon being initially partially constrained against inflation by a slidable constraint surrounding a portion of said balloon, said constraint configured such that the injection of fluid into said balloon causes said constraint to slide axially along said balloon, permitting inflation of further portions of said balloon, and

a tubular prosthesis disposed on said catheter over at least a portion of said balloon and a portion of said constraint, said tubular prosthesis having a contracted condition and an expanded condition, said tubular prosthesis being initially disposed on said catheter in said contracted condition.

2. The prosthesis delivery system of claim 1 wherein said sheath is designed to axially slide along a length of said balloon such that said balloon may be progressively incrementally inflated.

3. The prosthesis delivery system of claim 2 wherein said slidable sheath is adapted to slide axially onto a shaft of said catheter so that said sheath may be retrieved from a patient with said shaft.

4. The prosthesis delivery system of claim 1 wherein said tubular prosthesis is a stent.

7. The prosthesis delivery system of claim 6 wherein said axially slidable sheath is formed of a low coefficient of friction polymer.